



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Vince Contreras, Ph.D., 240-669-2823; vince.contreras@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Recombinant Nipah F Proteins and Their Use

Description of Technology:

Nipah virus is an emerging pathogenic paramyxovirus responsible for sporadic and isolated outbreaks of severe respiratory and neurologic disease in Southern Asia. As a

zoonotic virus, disease can manifest in both animals and human with indigenous fruit bats acting as natural reservoirs of the virus. The effects of viral infection vary from acute respiratory distress to fatal encephalitis. There are currently no approved therapeutics or vaccines against the virus, and growing concerns that this highly pathogenic infection has the potential to cause larger epidemics capable of inflicting significant mortality burden. Like the RSV fusion (F) glycoprotein, the Nipah fusion glycoprotein is a target of neutralizing antibodies that mediate protection against infection. Previous studies of prefusion-stabilized F glycoproteins from pneumoviruses and other paramyxoviruses (e.g. RSV and PIVs) have shown they elicit higher titers of neutralizing antibodies in both animals and humans than post-fusion F proteins.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) designed disulfide, cavity-filling and other mutations that stabilize the Nipah F glycoprotein in the prefusion conformation and bind prefusion-specific antibodies. These mutations also increase protein expression yields up to 50-fold making the recombinant proteins easy to manufacture and amenable to the use of genetic immunization using nucleic acid or vector-based applications.

The stabilized prefusion state of the Nipah F glycoprotein may be an ideal vaccine immunogen to elicit broad potent Nipah neutralizing antibodies. First and second generation prefusion molecules have been designed and tested in small animals and results (immunogenicity and stability) appear promising.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404.

Potential Commercial Applications:

- Vaccine - to elicit potent neutralizing antibodies against the Nipah Env glycoprotein.

Competitive Advantages:

Nipah prefusion F design has the following features compared to wild-type fusion glycoprotein:

- Robust stabilization.
- Up to 50-fold increase in expression yields, making the recombinant proteins easy to manufacture.
- Potential to link the recombinant glycoprotein to nanoparticles or oligomerization peptides.

Development Stage: *In vivo* testing (rodents).

Inventors: Barney S. Graham (NIAID), Rebecca J. Loomis (NIAID), Guillaume Stewart-Jones (NIAID), John R. Mascola (NIAID), and Jason McLellan (NIAID).

Intellectual Property: HHS Reference Number E-050-2018 includes U.S. Provisional Patent Application Number 62/714,230 filed 08/03/2018.

Related Intellectual Property: PCT Application No. PCT/US2008/087719 filed 19/12/2008.

Licensing Contact: Vince Contreras, Ph.D., 240-669-2823; vince.contreras@nih.gov

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Suzanne M. Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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